

## **REMARKS**

Reconsideration of the claims of the instant application is respectfully requested in view of the above amendments and the following remarks. Claims 1, 25, 26, and 27 have been amended. The support for the amendments may be found at least in the previously submitted claims. Claim 22 has been cancelled without prejudice. Previously withdrawn claims 2, 5-14, 17-21, 23, and 24 have also been cancelled. Claims 1, 3, 4, 15, 16, and 25-30 are now in this case. The drawings of the instant application have been replaced. The only differences between the replacement drawings submitted herewith and the previously submitted drawings are in Fig. 1: the “F” at position 64 has been replaced with “P”, and the length of prohepcidin has been amended from “aa25-94” to “aa25-84.” The support for these amendments is found at least in SEQ ID NO: 2 and Fig. 7. Accordingly, no new matter is introduced with this response.

The instant invention is drawn, in one aspect, to a method for diagnosing a condition of a disease characterized by non-physiological levels of hepcidin, comprising obtaining a tissue or fluid sample from a subject; contacting the sample with an antibody or fragment thereof that specifically binds to one or more carboxy terminal epitopes of SEQ ID NO: 2, and quantifying hepcidin level in the sample; wherein the disease is selected from chronic renal insufficiency, renal anemia and hereditary hemochromatosis; the tissue or fluid sample is selected from kidney samples, liver samples, and urine samples; and the non-physiological level of hepcidin is indicative of the disease.

### **A. Objection to the figures.**

The Examiner objected the figures of the instant application because of a typographical error which results in an incorrect length of prohepcidin (i.e., reciting amino acids 25-94 instead of amino acids 25-84). Applicants thank the Examiner for noticing this typographical error. The replacement figures have been provided with this response. The only differences between the figures submitted herewith and the figures submitted in response to the Office Action of January 25, 2008 are the corrected length of prohepcidin and replacement of “F” with “P” at position 64 of the sequence illustrated in Fig. 1. The support for the amendment is found at least in Fig. 7 of the application. Accordingly, Applicants respectfully submit that this objection ground has been overcome.

**B. Rejections based on 35 U.S.C. § 112, first paragraph (enablement)**

The Examiner rejected the claims of the instant application as non-enabled due to multiple reasons, each of which will be discussed in turn.

**1. Rejection of claims 1, 3, 4, 15, 16, 22, 25-30.**

The Examiner rejected aforementioned claims because, allegedly, the detection of hepcidin in blood samples is not enabled. Without agreeing with the Examiner and solely for expediting prosecution of the instant application, independent claims 1 and 27 have been amended to exclude blood samples. Accordingly, this rejection ground has been overcome.

**2. Rejection of claims 1, 3, 4, 15, 16, 22, 25, and 26.**

The Examiner rejected aforementioned claims because, allegedly, the only diseases whose diagnostics is enabled are renal anemia, chronic insufficiency anemia and hereditary hemochromatosis. Applicants respectfully disagree and politely point out that limiting the diseases to only those recited in the specification is contrary to MPEP § 2164.08 which states that

[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

In this case, Applicants have provided a list of the articles showing correlation of altered hepcidin amount to specific condition, or showing connection between blood iron content and hepcidin, and the connection between the disease and blood iron content. Thus, from these articles, a person of ordinary skill in the art may reasonably conclude that these disease correlate with abnormal hepcidin level.

Applicants respectfully note that the enablement requirement should be viewed from the position of one of ordinary skill in the art (MPEP § 2164.01(a)) and in this field, the ordinary skill is undeniably high. Accordingly, a person of ordinary skill would be capable of making reasonable correlations between the disease recited in the previously submitted articles and hepcidin levels. Applicants further respectfully point out that "The evidence provided by applicant need not be conclusive but merely convincing to one skilled in the art." MPEP §

2164.05. Accordingly, Applicants respectfully submit that the Examiner's argument that the specification lacks specific experimental data for each and every disease recited in the previously presented claims calls for the conclusive correlation, which ins contrary to MPEP.

Nevertheless, in order to expedite the prosecution of the instant application, the list of diseases has been limited to renal anemia, chronic insufficiency anemia and hereditary hemochromatosis. As admitted in this Office Action, the correlation between altered level of hepcidin and these diseases has been demonstrated in this specification. Accordingly, Applicants respectfully request the Examiner to withdraw this rejection ground.

### **3. Rejection of claims 27-30**

The Examiner rejected claims 27-30 because, allegedly, the instant application enabled the detection only by Western blot, immunodot, immunohistochemistry, and immunofluorescence assays. Without agreeing with the Examiner and solely for expediting the prosecution of the instant application, claim 27 has been amended to recite the aforementioned assays. Accordingly, Applicants respectfully request the Examiner to withdraw this rejection ground.

In view of the amendments to the claims and the arguments above, Applicants respectfully submit that the instantly submitted claims fully comply with the enablement requirement, and accordingly, Applicants respectfully request the Examiner to withdraw this rejection ground.

### **C. Rejection based on 35 U.S.C. § 112, second paragraph.**

The Examiner rejected the claims of the instant application as allegedly indefinite. Specifically, the Examiner argues that in the independent claim 1, it is unclear whether "applicant is diagnosing a condition of a disease or if application is detecting a disease." Applicants respectfully disagree. MPEP § 2173.02 requires only that claims should define the invention with a "reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire." (emphasis in the original). Applicants further note that MPEP § 2173.02 specifies that the compliance with the second paragraph of §

112 is viewed from the perspective of a person having ordinary skill in the art, and in this art, the level of ordinary skill is high.

Applicants respectfully submit that it is sufficiently clear that the method of claim 1 calls for (a) detection of hepcidin level; and (b) diagnosis of the disease recited in claim 1 based on the level of hepcidin as detected in step (a).

Applicants further respectfully note that the term “disease” as used in claim 1, fully complies with the antecedent bases requirement. Accordingly, Applicants respectfully request a withdrawal of the instant ground of rejection of claim 1 and claims dependent therefrom.

The Examiner also rejected claim 27 because, allegedly, the preamble of the claim does not correlate with the body of the claim. The Examiner further makes requirements regarding the form of claim 27. Applicants respectfully note that the requirements set forth on page 14 of the Office Action do not appear to be based on the MPEP, at least because they contradict MPEP § 2173.01. That section states that “Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought.” Thus, the rigid requirements posed by the Examiner are contrary to MPEP.

Applicants further respectfully disagree with the assertion that the preamble of the claim does not correlate with the body of the claim. The preamble recites “detecting” hepcidin, and the body of the claim provides the steps necessary for detection, namely, providing the sample containing hepcidin, and contacting this sample with the antibody that detects hepcidin. Applicants respectfully maintain that MPEP § 2173.02 specifies that the compliance with the second paragraph of § 112 is viewed from the perspective of a person having ordinary skill in the art, and in this art, the level of ordinary skill is high. Accordingly, a person of ordinary skill in the art would be capable of reasonably determine the metes and bounds of claim 27. As discussed above, nothing more is required by MPEP § 2173.02.

Accordingly, in view of the arguments above, Applicants respectfully request the Examiner to withdraw this ground for rejection of claim 27 and the claims dependent therefrom.

**CONCLUSION**

In view of these amendments and remarks, applicants believe that this application is in a condition for allowance and an early notice to this effect is earnestly solicited. If the Examiner does not believe that such action can be taken at this time or if the Examiner feels that a telephone interview is necessary or desirable, Applicants welcome the Examiner to call the undersigned at 609-844-3021.

The USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

Respectfully submitted,

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